Remarks

I. Supplemental Information Disclosure Statements.

A second Supplemental Information Disclosure Statement (IDS) accompanies this Preliminary Amendment. The IDS includes a modified form 1449. No copies of U.S. Patents are provided; however, copies of literature references accompany this paper. A first Information Disclosure Statement was submitted on 24 July 2003. A Supplemental Information Disclosure Statement was submitted 6 November 2003. Applicants request that the Examiner indicate that the references have been considered by initialing each cited reference on each of the modified form 1449s and returning copies of the initialed forms to the applicants.

Applicants note that three patents have been issued by the USPTO from applications to which the present application claims priority, i.e., U.S. Patent Nos. 6,180,416, 6,326,160, and 6,653,091. These three patents have all been recited in the Information Disclosure Statements.

Conclusion

Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. §112 and define an invention that is patentable over the art. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Please direct all further communications in this application to:

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If the Examiner notes any further matters that the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned at (650) 599-3526.

Respectfully submitted,

Date: 22 June 2004 By: Gary R Fabian

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AMENDMENTS TO THE CLAIMS

(including complete listing of the claims)

1. (Currently Amended) The method of claim 28, wherein for the Mixtures of Experts algorithm the individual experts have a linear form

$$An = \sum_{i=1}^{n} An_i w_i \qquad (1)$$

wherein (An) is an analyte of interest, n is the number of experts, An_i is the analyte predicted by Expert i; and w_i is a parameter, and the individual experts An_i are further defined by the expression shown as Equation (2)

$$An_i = \sum_{j=1}^{m} a_{ij} P_j + z_i \qquad (2)$$

wherein, An_i is the analyte predicted by Expert i; P_j is one of m parameters, m is typically less than 100; a_{ij} are coefficients; and z_i is a constant; and further where the weighting value, w_i, is defined by the formula shown as Equation (3)

$$w_i = \frac{e^{d_i}}{\left[\sum_{k=1}^{n} e^{d_k}\right]} \qquad (3)$$

where e refers to the exponential function, d_i is one of the d_k, d_i and d_k are parameter sets analogous to Equation 2 used to determine the weight w_i, the ~~and~~ dk are given by Equation 4

$$d_k = \sum_{j=1}^{m} \alpha_{jk} P_j + \omega_k \qquad (4)$$

where α_{jk} is coefficient, P_j is one of m parameters, and where ω_k is a constant.

2-4. (Canceled)

5. (Previously Presented) The method of claim 25, wherein the analyte is glucose.

6-14. (Canceled)

15. (Currently Amended) A monitoring system for measuring an amount or concentration of analyte present in a biological system, said system comprising, in operative combination:

a sensing device in operative contact with the analyte, wherein said sensing device obtains a raw signal from the analyte and said raw signal is specifically related to the amount or concentration of analyte; and

one or more microprocessors in operative communication with the sensing device, wherein said one or more microprocessors comprises programming to control

(i) operation of the sensing device; and

$$\cancel{An = \sum_{i=1}^{n} An_i w_i \qquad (1)}$$

$$\cancel{An_i = \sum_{j=1}^{m} a_{ij} P_j + z_i \qquad (2)}$$

$$\cancel{w_i = \frac{e^{d_i}}{\left[\sum_{k=1}^{n} e^{d_k}\right]} \qquad (3)}$$

$$\cancel{d_k = \sum_{j=1}^{m} \alpha_{jk} P_j + \omega_k \qquad (4)}$$

(ii) providing two or more ranges of measurement values, wherein said measurement values are indicative of amounts or concentrations of analyte present in the biological system;

identifying the range in which a selected measurement value falls; and

employing an algorithm for prediction of further measurement values wherein said algorithm is optimized for performance in the identified range.

16-24. (Canceled)

25. (Currently Amended) A method for measuring an amount or concentration of analyte present in a biological system, said method comprising:

determining a measurement value indicative of the amount or concentration of analyte present in the biological system;

providing two or more ranges of measurement values;

identifying the range in which said determined measurement value falls;

employing an algorithm for prediction of further measurement values wherein said algorithm is optimized for performance in the identified range; and

generating further measurement values indicative of ~~measuring~~ amount or concentration of analyte present in the biological system using said algorithm.

26. (Previously Presented) The method of claim 25, wherein said determining a measurement value indicative of the amount or concentration of analyte present in the biological system comprises obtaining a raw signal specifically related to analyte amount or concentration in the biological system and correlating the raw signal with a measurement value.

27. (Previously Presented) The method of claim 25, wherein said determining is carried out using a Mixtures of Experts and said Mixtures of Experts algorithm is trained using a global training set.

28. (Previously Presented) The method of claim 25, wherein said algorithm for

prediction of further measurement values is a Mixtures of Experts algorithm and said Mixtures of Experts algorithm is trained using data from the identified range.

29. (Previously Presented) The method of claim 25, further comprising identifying in which range one or more of the further measurement values falls, and

employing an algorithm for prediction of further measurement values wherein said algorithm is optimized for performance in the identified range.

30. (Previously Presented) One or more microprocessors for us in an analyte monitoring system for measuring an amount of concentration of analyte present in a biological system, said one or more microprocessors comprising programming to control:

providing two or more ranges of measurement values, wherein said measurement values are indicative of amounts or concentration of analyte present in the biological system;

identifying the range in which a selected measurement value falls, and

employing an algorithm for prediction of further measurement values wherein said algorithm is optimized for performance in the identified range.

31. (Previously Presented) The one or more microprocessors of claim 30, wherein a Mixtures of Experts algorithm is used to determine said selected measurement value and said Mixtures of Experts algorithm is trained using a global training set.

32. (Previously Presented) The one more microprocessors of claim 30, wherein said algorithm for prediction of further measurement values is a Mixtures of Experts algorithm and said Mixtures of Experts algorithm is trained using data from the identified range.

33. (Previously Presented) The one or more microprocessors of claim 30, wherein said or more microprocessors are further programmed to control operation of a sensing device that provides raw signal specifically related to analyte amount or concentration in the biological system.

34. (Previously Presented) The one or more microprocessors of claim 33, wherein

said one or more microprocessors are further programmed to control correlating the raw signal with a measurement value indicative of analyte amount or concentration in the biological system.

35. (Currently Amended) The one or more microprocessors of claim 32, wherein for the Mixtures of Experts algorithm the individual experts have a linear form

$$An = \sum_{i=1}^{n} An_i w_i \qquad (1)$$

wherein (An) is an analyte of interest, n is the number of experts, An_i is the analyte predicted by Expert i; and w_i is a parameter, and the individual experts An_i are further defined by the expression shown as Equation (2)

$$An_i = \sum_{j=1}^{m} a_{ij} P_j + z_i \qquad (2)$$

wherein, An_i is the analyte predicted by Expert i; P_j is one of m parameters, m is typically less than 100, a_{ij} are coefficients; and z_i is a constant; and further where the weighting value, w_i, is defined by the formula shown as Equation (3)

$$w_i = \frac{e^{d_i}}{\left[\sum_{k=1}^{n} e^{d_k}\right]} \qquad (3)$$

where e refers to the exponential function, d_i is one of the d_k, d_i and d_k are parameter sets analogous to Equation 2 used to determine the weight w_i, the ~~and~~ dk are given by Equation 4

$$d_k = \sum_{j=1}^{m} \alpha_{jk} P_j + \omega_k \qquad (4)$$

where α_{jk} is a coefficient, P_j is one of m parameters, and where ω_k is a constant.

36. (Previously Presented) The one ore more microprocessors of claim 30, wherein the analyte is glucose.

37. (Previously Presented) The monitoring system of claim 15, wherein a Mixtures of Experts algorithm is used to determine said selected measurement value and said Mixtures of Experts algorithm is trained using a global training set.

38. (Previously Presented) The monitoring system of claim 15, wherein said algorithm for prediction of further measurement values is a Mixtures of Experts algorithm and said Mixtures of Experts algorithm is trained using data from the identified range.

39. (Previously Presented) The monitoring system of claim 15, wherein said sensing device provides a raw signal specifically related to analyte amount or concentration in the biological system and said one or more microprocessors are further programmed to control correlating the raw signal with a measurement value indicative of analyte amount or concentration in the biological system.

40. (Currently Amended) The monitoring system of claim 15, wherein for the Mixtures of Experts algorithm the individual experts have a linear form

$$An = \sum_{i=1}^{n} An_i w_i \qquad (1)$$

wherein (An) is an analyte of interest, n is the number of experts, An_i is the analyte predicted by Expert i; and w_i is a parameter, and the individual experts An_i are further defined by the expression shown as Equation (2)

$$An_i = \sum_{j=1}^{m} a_{ij} P_j + z_i \qquad (2)$$

wherein, An_i is the analyte predicted by Expert i; P_j is one of m parameters, m is typically less than 100; a_{ij} are coefficients; and z_i is a constant; and further where the weighting value, w_i, is defined by the formula shown as Equation (3)

$$w_i = \frac{e^{d_i}}{\left[\sum_{k=1}^{n} e^{d_k}\right]} \qquad (3)$$

where e refers to the exponential function, d_i is one of the d_k, <u>d_i and d_k are parameter sets analogous to Equation 2 used to determine the weight w_i, the</u> ~~and~~ dk are given by Equation 4

$$d_k = \sum_{j=1}^{m} \alpha_{jk} P_j + \omega_k \qquad (4)$$

where α_{jk} is a coefficient, P_j is one of m parameters, and where ω_k is a constant.

41. (Previously Presented) The monitoring system of claim 15, wherein the analyte is glucose.

42. (New) The method of claim 25, wherein said generating further measurement values indicative of amount or concentration of analyte present in the biological system comprises obtaining a raw signal specifically related to analyte amount or concentration in the biological system and using said algorithm to correlate the raw signal with a measurement value.

43. (New) The method of claim 25, wherein said determining a measurement value indicative of the amount or concentration of analyte present in the biological system comprises a calibration step.

44. (New) The method of claim 43, wherein said calibration step correlates a raw

signal obtained from a sensing device with a concentration of analyte present in the biological system.

45. (New) The method of claim 44, wherein said calibration step provides a calibrated signal by a method comprising

$$signal = \frac{BG_{cp}}{active_{cp}}(active)$$

wherein, *signal* is the calibrated signal, BG_{cp} is blood glucose value at a calibration point, $active_{cp}$ is an active signal that corresponds to an electrochemical sensor signal at the calibration point, and *active* is an active signal that corresponds to an electrochemical sensor signal.

46. (New) The method of claim 44, wherein said calibration step provides a calibrated signal by a method comprising

$$signal = \frac{BG_{cp}}{(active_{cp} + offset)}(active + offset)$$

wherein, *signal* is the calibrated signal, BG_{cp} is blood glucose value at a calibration point, $active_{cp}$ is an active signal that corresponds to an electrochemical sensor signal at the calibration point, *active* is an active signal that corresponds to an electrochemical sensor signal, and *offset* is a value that takes into account a non-zero y-intercept value.

47. (New) A method of calibrating an analyte monitoring device for use in measuring analyte amount or concentration in a biological system, said method comprising

determining a calibration ratio (CalRatio) value, wherein

$$CalRatio = \frac{BG_{cp}}{(active_{cp} + offset)}$$

wherein BG_{cp} is a blood glucose concentration at the calibration point, , $active_{cp}$ is an active signal that corresponds to an electrochemical sensor signal at the calibration point, and *offset* was a constant value;

providing two or more ranges of CalRatio values;

identifying the range in which said determined CalRatio value falls;

employing an algorithm for prediction of further measurement values wherein said algorithm is optimized for performance in the identified range; and

generating further measurement values indicative of amount or concentration of analyte present in the biological system, said generating comprising obtaining a raw signal specifically related to analyte amount or concentration in the biological system and using said algorithm to correlate the raw signal with a measurement value.

48. (New) One or more microprocessors for us in an analyte monitoring system for measuring an amount of concentration of analyte present in a biological system, said one or more microprocessors comprising programming to control:

determining a calibration ratio (CalRatio) value, wherein

$$CalRatio = \frac{BG_{cp}}{(active_{cp} + offset)}$$

wherein BG_{cp} is a blood glucose concentration at the calibration point, $active_{cp}$ is an active signal that corresponds to an electrochemical sensor signal at the calibration point, and *offset* was a constant value;

providing two or more ranges of CalRatio values;

identifying the range in which said determined CalRatio value falls;

employing an algorithm for prediction of further measurement values wherein said algorithm is optimized for performance in the identified range; and

generating further measurement values indicative of amount or concentration of analyte present in the biological system, said generating comprising obtaining a raw signal specifically related to analyte amount or concentration in the biological system and using said algorithm to correlate the raw signal with a measurement value.

49. (New) A monitoring system for measuring an amount or concentration of analyte present in a biological system, said system comprising, in operative combination:

a sensing device in operative contact with the analyte, wherein said sensing device obtains a raw signal from the analyte and said raw signal is specifically related to the

amount or concentration of analyte; and

one or more microprocessors in operative communication with the sensing device, wherein said one or more microprocessors comprises programming to control

(i) operation of the sensing device; and

(ii) determining a calibration ratio (CalRatio) value, wherein

$$CalRatio = \frac{BG_{cp}}{(active_{cp} + offset)}$$

wherein BG_{cp} is a blood glucose concentration at the calibration point, $active_{cp}$ is an active signal that corresponds to an electrochemical sensor signal at the calibration point, and *offset* was a constant value;

providing two or more ranges of CalRatio values;

identifying the range in which said determined CalRatio value falls;

employing an algorithm for prediction of further measurement values wherein said algorithm is optimized for performance in the identified range; and

generating further measurement values indicative of amount or concentration of analyte present in the biological system, said generating comprising obtaining a raw signal specifically related to analyte amount or concentration in the biological system and using said algorithm to correlate the raw signal with a measurement value.